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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,740	05/30/2006	Abilio Melquiades Laguna Granja	CLAIM.P003	7047
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LACKENBACH SIEGEL, LLP LACKENBACH SIEGEL BUILDING 1 CHASE ROAD SCARSDALE, NY 10583			EXAMINER CLARK, AMY LYNN	
			ART UNIT 1655	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,740	<b>Applicant(s)</b> LAGUNA GRANJA ET AL.	
	<b>Examiner</b> Amy L. Clark	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-16 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) 26-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on 10/13/2009 with the amendment of claims 14 and 15, and newly added claims 26-30.

### ***Election/Restrictions***

Newly submitted claims 26-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally examined claims were drawn to a pharmaceutical composition obtained from green or mature fruits of *Roystonea regia* comprising a mixture of specific fatty acids, with a specific range of carbon atoms and further having a specific fatty acid profile. Newly added claims 26-30 broaden the claims substantially and a search for the newly added claims is not co-extensive with a search for the subject matter of the originally examined claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 14 and 15 are under examination.**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (newly applied as necessitated by amendment).

In the amended claim 15, Applicant claims, that each of the fatty acids is present in the composition in an amount "by wt.", which is considered to be new matter. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly presented phrase, "by wt". The specification as originally filed only describes the amounts of each fatty acid in specific amounts or in a table of ranges and the claims, as originally filed, do not mention amounts by weight. This is not sufficient support for the new phrase: "by wt". This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

### ***Claim Rejections - 35 USC § 102/103***

Claims 14 and 15 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over El-Khalaty et al. (Applicants' IDS NPL Reference 4).

El-Khalaty teaches an oil fraction obtained from *Oreodoxa regia* (royal palm) (which is synonymous with *Roystonea regia*) seeds (which reads on fruit, since the royal palm seed contains the fruit) comprising caprylic acid in an amount of 0.4%, capric acid in an amount of 0.4%, lauric acid in an amount of 11.1%, myristic acid in an amount of 5.5%, palmitic acid in an amount of 22.2%, palmitoleic acid in an amount of 9.8%, stearic acid in an amount of 3.0%, oleic acid in amount of 35.3%, linoleic acid in an amount of 17.3% and linolenic acid in amount of 3.5% (See table IV, page 273), which

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read on the ranges of each fatty acid component of Applicants' pharmaceutical composition in claim 15. El-Khalaty further teaches that the oil is obtained through a process of first crushing the seed, then defatting the seed followed by subjecting the resulting seed meal to acidic and alkaline hydrolysis (See page 270).

Although El-Khalary does not expressly teach that the oil fraction is a pharmaceutical nor does El-Khalary teach that the composition comprises a mixture of esters of the fatty acids nor does El-Khalary teach that free fatty acids are enriched from ester hydrolysis, the claimed functional properties are inherent to the preparation taught by El-Khalary. The functional properties are inherent to the preparation taught by El-Khalary because the El-Khalary expressly teaches the same composition taught by Applicants based upon the fatty acid profile provided by El-Khalary and the method taught by El-Khalary of obtaining the fatty acid profile from the seeds of royal palm are one and the same as disclosed in the instantly claimed invention of Applicants. Thus, the oil fraction obtained from seeds of royal palm as taught by El-Khalary, a mixture of esters of the fatty acids, and free fatty acids enriched from ester hydrolysis are inherent to the oil fraction composition taught by El-Khalary. Therefore, the reference anticipates the claimed subject matter.

In the alternative, even if the oil fraction composition obtained from *Oreodoxa regia* (royal palm) (which is synonymous with *Roystonea regia*) seeds comprising caprylic acid in an amount of 0.4%, capric acid in an amount of 0.4%, lauric acid in an amount of 11.1%, myristic acid in an amount of 5.5%, palmitic acid in an amount of 22.2%, palmitoleic acid in an amount of 9.8%, stearic acid in an amount of 3.0%, oleic

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acid in amount of 35.3%, linoleic acid in an amount of 17.3% and linolenic acid in amount of 3.5% taught by El-Khalary is not identical to the pharmaceutical composition claimed by Applicants with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the oil fraction composition taught by El-Khalary is likely to intrinsically possess the same characteristics (including with respect to the instantly claimed functional effects) of the pharmaceutical composition claimed particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed pharmaceutical composition obtained from the fruit of *Roystonea regia* would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Accordingly, the claimed invention as a whole was at *least prima facie* obvious, if not anticipated by El-Khalary, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's claimed pharmaceutical composition is different from the oil fraction composition taught by El-Khalary and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

### ***Response to Arguments***

Applicants' arguments concerning the 35 U.S.C. § 102(b)/103(a) rejection above have been thoroughly considered but are not deemed persuasive of error in the rejection.

Applicants argue that El-Khalaty et al. is directed to an extraction from the seeds only, which seed oil is intended to be used in a food product and that the present invention is directed to the whole fruit. Applicants further argue that the present extract is derived from the whole fresh or dried fruit to provide a pharmaceutical composition for e.g. treatment of BPH in a male mammal. Applicants further argue that the profile of fatty acids taught by El-Khalaty is different than that claimed by Applicants.

However, this is not found persuasive because according to "Everyday mysteries: Fun Science Facts from the Library of Congress" (Reference V), botanically speaking, a coconut is a fibrous one-seeded drupe, also known as a dry drupe, but that when using loose definitions, the coconut can be a fruit, a nut and a seed. "The Free Dictionary: palm" (Reference W) teaches that the seed size of the palm varies, as does the trunk height and diameter and the leaf length and that the fruits of palms, covered with a tough fleshy, fibrous, or leathery outer layer, usually contain a large amount of endosperm in the seed (stored food) (please note that "Everyday mysteries: Fun Science Facts from the Library of Congress" teaches Some scientists like to refer to the coconut as a water dispersal fruit and seed and that that in addition to the "baby" plant in the seed, there is the food to kick off its life called the endosperm. The endosperm is what makes up most of the seed and, in the coconut's case, is the yummy white stuff we eat, which reads on fruit). "The Free Dictionary: palm oil" teaches that

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palm oil is the fat pressed from the fibrous flesh of the fruit of many palms. Therefore, it is understood in the art that "seed" can be used interchangeably to mean the fruit of the palm. El-Khalaty also uses this term loosely throughout the introduction, for example El-Khalaty teaches that "the characteristics and fatty acid composition of the *Oreodexa regia* (royal palm) oil from a lot of nuts from Cuba were studied by Stillman et al, and the constants of the oil were fat content (of the kernel)...the fatty acid composition of the oil was..." which demonstrates a difference between the seed as a whole (which contains the fruity pulp of the royal palm) and the kernel. El-Khalaty further teaches that seeds and kernels were investigated in the extraction of oil (See page 270). Finally, Stillman (Reference U, prior art of record) teaches that the nut of the Cuban palm contains 25% oil and that upon further examination, the ripe fruit of the Cuban palm contains the same oil as that obtained from the kernel of the Cuban palm (again, demonstrating that "seed" contains fruit) and describes saponifying the oil and fractioning the oil to obtain a fatty acid profile. Therefore, it would be expected that at the very least the fatty acid profile of the fruit and of the seed (if there is indeed a difference) would be the same or similar between the oil obtained from the kernel and the fruit and the profile of the whole of the seed would be expected to be consistent with the profile of oil obtained from the fruit and the profile of the oil obtained from the kernel. Therefore, El-Khalaty reads at least on a mixture of primary fatty acids with 8 to 28 carbon atoms obtained from ripe fruit of *Roystonea regia* (synonymous with Cuban palm and Cuban palmetto), and at the very least anticipates the subject matter of claim 1, which does not recite exact amounts of each fatty acid and does not require that all of the fatty acids in the claim be present in

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the composition. Further, the method of obtaining the extract from El-Khalaty appears to be identical to the process, as claimed, by which Applicants have obtained their extract of the Cuban palm fruit and would be expected to contain a similar profile. Optimizing one particular fatty acid would have been obvious to one of ordinary skill in the art (as set forth above and in the previous Office Action).

In order to help overcome the prior art of record, Applicant is invited to amend the claims by inserting an intended use of the composition, inserting the process by which the specific fatty acid profile of claim 15 is obtained (for example, the method steps illustrated in Examples 1-3 of the specification), inserting the specific fatty acid profile of claim 15 into claim 14 (please note Applicants should also insert the fatty acid profile in claim 15 into the specification, since the originally filed specification does not contain this particular profile, however, this profile is found in the originally filed claims so insertion of this profile would not constitute new matter), removing "by weight" from the profile of claim 15 and inserting the phrase "effective amount" into the preamble.

An example of the newly drafted claim would read:

A pharmaceutical composition for treating BPH (benign prostatic hyperplasia) comprising an effective amount of a Roystonea regia extract wherein the extract is obtained by the process of:

- i.) drying green or mature fruits of Roystonea regia;
- ii.) grinding the dried fruit into a powder;
- iii.) subjecting the powder to alkaline hydrolysis; and
- iv.) extracting the hydrolyzed powder with an organic solvent, whereby the

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extract comprises a mixture of primary fatty acids with 8 to 28 carbon atoms, wherein the fatty acids comprise caprylic acid (C8:0) in an amount of <3.0 %, capric acid (C10:0) in an amount of <3.0%, lauric acid (C12:0) in an amount of 3.0-40.0%, miristic acid (C14:0) in an amount of 4.0-15.0%, palmitic acid (C16:0) in an amount of 10.0-80.0%, palmitoleic acid (C16:1) in an amount of 1.5-20.0%, stearic acid (C18:0) in an amount of 0.1-5.0% and oleic acid (C18:1) in an amount of 3.0-50.0%.

As currently drafted, the claims remain rejected for the reasons of record and for the reasons set forth above.

### ***Conclusion***

**No claims are allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy L Clark/

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